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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,097

04/13/2004

Steve J.D. Bell

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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,097	Applicant(s) BELL, STEVE J.D.	
	Examiner ROBERT A. ZEMAN	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-27-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-27-2007 has been entered.

The amendment and response filed on 1-10-2008 are acknowledged. Claim 10 has been amended. Claims 1-9, 13-24 and 26 have been canceled. Claims 27-30 have been added. Claims 10-12 and 27-30 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 8-27-2007 has been considered. An initialed copy is attached hereto.

Priority

As parent application 09/496,771 does not disclose the use of calcium phosphate particles to deliver allergens, the filing date of application 09/932,538 (8-17-2001) will be used for determining the availability of art with regard to this limitation. Applicant's argument that the skilled artisan would know that an allergen is an immunogen is not germane. Since the parent application does not disclose or contemplate the use of allergens, it cannot provide support for instant claims 28-30.

Claim Rejections Withdrawn

The rejection of claims 10-12 under 35 U.S.C. 102(b) as being anticipated by Lee et al. (WO 00/15194 – IDS) is withdrawn in light of the amendment thereto. Said amendment makes the aforementioned reference unavailable as art under 35 U.S.C. 102(b).

New Grounds of Rejection

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Relyveld et al. (Annals of Allergy, 1985, Vol. 54, pages 521-529 – IDS filed on 10-21-2004).

Relyveld et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 522). Moreover, Relyveld et al. disclose that said adsorbed particles were injected subcutaneously (see page 522).

Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Relyveld et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and

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functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Claims 10-11 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ickovic et al. (Annals of Immunology (Inst. Pasteur), 1983, 134 D, pages 385-398 – IDS filed on 10-21-2004).

Ickovic et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 387-388). Moreover Ickovic et al. disclose that said adsorbed particles were injected subcutaneously (see page 387). Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Ickovic et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Claims 10-11 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuwayser (U.S. Patent 5,648,097 – IDS files on 10-21-2004).

Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles

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are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens, desensitizing agents and antiallergenic (see column 6, lines 9-13). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Relyveld et al. (Annals of Allergy, 1985, Vol. 54, pages 521-529 – IDS filed on 10-21-2004).

Relyveld et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 522). Moreover, Relyveld et al. disclose that said adsorbed particles were injected subcutaneously (see page 522).

Additionally, with regard to the surface irregularity limitation of claim 29, it is deemed in absence of evidence to the contrary that since the compositions of Relyveld et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for

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examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Relyveld et al. differs from the instant invention in that he doesn't explicitly disclose the use of their calcium phosphate particles delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]).

Claims 10-12 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ickovic et al. (Annals of Immunology (Inst. Pasteur), 1983, 134 D, pages 385-398 – IDS filed on 10-21-2004).

Ickovic et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 387-388). Moreover Ickovic et al. disclose that said adsorbed particles were injected subcutaneously (see page 387). Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Ickovic et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art

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reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Ickovic et al. differs from the instant invention in that he doesn't explicitly disclose the use of their calcium phosphate particles delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]).

Claims 10-12 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser (U.S. Patent 5,648,097 – IDS files on 10-21-2004).

Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens, desensitizing agents and antiallergenic (see column 6, lines 9-13). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

.Nuwayser differs from the instant invention in that he doesn't explicitly disclose the use of his "microparticles" delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

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through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
April 8, 2008